

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 17 JAN 2000

WIPO PCT

Applicant's or agent's file reference 9403-2 PC	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/16383	International filing date (day/month/year) 06 AUGUST 1998	Priority date (day/month/year) 07 AUGUST 1997
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant GUPTA, AJAY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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Date of submission of the demand 29 JANUARY 1999	Date of completion of this report 02 DECEMBER 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MARY E. MOSHER, PH.D. Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (January 1994)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/16383

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

☒ the international application as originally filed.

☒ the description, pages 1-31, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of _____.

pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-50, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of _____.

Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig none, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of _____.

sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages none.

☒ the claims, Nos. none.

☒ the drawings, sheets/fig none.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/16383

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>1-43, 47-50</u>	YES
	Claims <u>44-46</u>	NO
Inventive Step (IS)	Claims <u>1-43, 47-50</u>	YES
	Claims <u>44-46</u>	NO
Industrial Applicability (IA)	Claims <u>1-50</u>	YES
	Claims <u>none</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 44-46 lack novelty under PCT Article 33(2) as being anticipated by Apatate® vitamin concentrate, as shown in the 1996 Physician's Desk Reference (PDR). Although the PDR does not teach the same intended use for the concentrate, the reference concentrate has the same ingredients as recited in the claims, and is capable of being used for the same purpose. Since these claims are drawn to a composition, not a method of use, the reference concentrate meets each and every claim limitation.

Claims 1-43 and 47-50 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest supplementation of dialysate solution with the components listed in the claims.

Claims 1-50 meet the criteria set out in PCT article 33(4) for industrial applicability.

_____ NEW CITATIONS _____

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/16383

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(6): A61M 1/14, 1/28; A61K 31/00, 31/44, 31/51, 31/68 and US Cl.: 210/645, 646; 604/29; 514/52,429,276

Copy for the Elected Office (EO/US)
PATENT COOPERATION TREATY

PCT/US98/16383

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE

(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

MONACO, Daniel, A.
Seidel, Gonda, Lavorgna & Monaco,
P.C.
Suite 1800
Two Penn Center Plaza
Philadelphia, PA 19102
ÉTATS-UNIS D'AMÉRIQUE

Date of mailing (day/month/year) 11 June 1999 (11.06.99)	
Applicant's or agent's file reference 9403-2 PC	IMPORTANT NOTIFICATION
International application No. PCT/US98/16383	International filing date (day/month/year) 06 August 1998 (06.08.98)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address GUPTA, Ajay 39151 Horton Drive Farmington Hills, MI 48331 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☐ the address ☒ the nationality ☐ the residence

Name and Address GUPTA, Ajay 39151 Horton Drive Farmington Hills, MI 48331 United States of America	State of Nationality IN	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Dominique DELMAS Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 10 May 1999 (10.05.99)	
International application No. PCT/US98/16383	Applicant's or agent's file reference 9403-2 PC
International filing date (day/month/year) 06 August 1998 (06.08.98)	Priority date (day/month/year) 07 August 1997 (07.08.97)
Applicant GUPTA, Ajay	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
29 January 1999 (29.01.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Sean Taylor

Telephone No.: (41-22) 338.83.38

09/367629
10 Rec'd PCT/PTO 19 AUG 1999

The PTO did not receive the following
listed item(s)
NO POST OFFICE

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
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BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
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CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/16383

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/14, 1/28; A61K 31/00, 31/44, 31/51, 31/68

US CL :210/645, 646; 604/29; 514/52,429,276

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/645, 646; 604/29; 514/52,429,276

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Physicians' Desk Reference. 1996. Page 1319, see Apatate® liquid, see entire document.	44-46
A	US 5,108,767 A (MULCHANDANI et al.) 28 April 1992.	1-43, 47-50
A	BOSTOM et al. High dose B-vitamin treatment of hyperhomocysteinemia in dialysis patients. Kidney International. January 1996. Vol. 49, pages 147-152.	1-43, 47-50
A	KASAMA et al. Vitamin B6 and Hemodialysis: The Impact of High-Flux/High Efficiency Dialysis and Review of the Literature. American Journal of Kidney Diseases. May 1996. Vol. 27, Number 5, pages 680-686.	1-43, 47-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

30 SEPTEMBER 1998

Date of mailing of the international search report

26 OCT 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MARY E. MOSHER, PH.D.

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/16383

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

APS, Medline, Derwent World Patents. Search terms: Dialysis, hemodialysis, peritone?, vitamin#, dialysate, solution, solutions, nutrient#, nutrition###, folic, folate, b6, thiamin#, b12, pyridox?, ?cobalamin, supplement?